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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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11/02/2001

Yung-Fu Chang

1258-006 CIP

9399

20874

7590

12/12/2006

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EXAMINER

MONTANARI, DAVID A

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 12/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/004,494

Applicant(s)

CHANG, YUNG-FU

Examiner

David Montanari

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1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 47 and 69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47 and 69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicants arguments and amendments filed 9/27/2006 have been entered.
2. A new examiner has taken over prosecution of the instant case.
3. Claims 47 and 69 are examined in the instant application.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 47 and 69 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 47 encompass recombinant DNA from any transgenic organism, the scope of which encompasses a human being, which is non-statutory subject matter. As such, the recitation of the limitation "isolated" would be remedial. See 1077 O.G. 24, April 21, 1987.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 47 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Lewis et al. (1994).

Applicants have cancelled claim 48 which is new claim 69. Claim 48 was rejected under 102(b) in the previous office action mailed on 6/27/2006. Based upon a reading of claim 69 it appears to be of the same scope of as cancelled claim 48. Further claim 47 was not rejected under 102(b) in the previous office action, however an examination of the previous 102(b) rejection would encompass claim 47 and it is now currently rejected. Further the previous rejection mailed on 6/27/2006 is reiterated below with regard to claims 47 and 69. If the vector is anticipatory then the recombinant DNA claims is as well. It is also noted that applicant has not presented any arguments regarding the 102(b) rejection of claim 48 in the previous office action, and that rather applicant has cancelled claim 48 and presented a new claim 69, which as discussed above is of similar scope.

Applicant notes the amendments to the independent claims and argue that the teaching of Lewis et al. fail to teach the use of the disclosed sequences for use in inducing an immune response to E. canis, nor does an inherent ability of the sequences necessarily flow from the teachings of Lewis et al. and fail to teach a "recombinant DNA" wherein the sequence elicits an immune response to E. canis. Applicants point to the declaration previously filed and note that post-filing experiments demonstrate that the disclosed sequences do induce an immune response when delivered as a DNA vaccine and provides the basis for immunogenic sequences. See pages 11-14, section b of Applicant's amendment. Applicant's arguments have been fully considered, but not found persuasive.

Again it is noted that Applicant does not argue the sequence of Lewis et al. does not share homology with the claimed sequences, only that it is not recombinant and that it will not induce an immune response to E. canis. Examiner acknowledges that the encoded protein sequences can

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be expressed and that they may be able to induce an immune response, however there is no clear teaching of what sequences are immunogenic. The teaching in the specification for identifying potential immunogenic portions of a protein is also acknowledged, however this is general guidance recognized in the art for identifying potential sequences applied to the specific sequences disclosed, and fails to include or exclude any specific sequence from being immunogenic. Given the guidance of the present specification and even the post-filing art there is no evidence to what portions of the disclosed sequences must be present to uniquely elicit an immune response to *E. canis*, therefore the Office is left to interpret the claims from a structural basis. Examiner would agree that Lewis et al. does not disclose the use of the sequences to induce an immune response to *E. canis*, however based on the homology and the ability of effectively any sequence to be immunogenic a reasonable interpretation from a structural point of view would be that homologous sequences capable of being immunogenic should meet the limitations of the instant claims. Examiner's reliance on inherency has been established in technical reasoning given the breadth of the claims directed to a product and the structural similarities of the claimed product and that disclosed in the prior art to anticipate structurally the embodiments of the instant claims.

The instant rejection has been made and maintained in light of the breadth of the claims in light of the guidance of the instant specification. With respect to the term recombinant, this is broad general term recognized in the art, and the cloning of the sequences out of the genome and their characterization as disclosed by Lewis et al. would constitute a recombinant sequence since it is out of the endogenous content. Further, it is noted that the sequence is manipulated as a

DNA molecule. The instant specification does not point to any specific sequence be necessary nor required for eliciting an immune response, nor do Applicant's arguments differentiate the breadth of the claimed sequences from that of Lewis et al. The claims broadly encompass any polynucleotide sequence which encodes an amino acid sequence that can elicit an immune response and vectors capable of expressing said protein. As suggested by Applicant, the rejection relies in part on inherency of the sequence, and given that sequences share structural similarity as demonstrated by their homology, and given the guidance of the instant specification, it is maintained that the sequence specifically disclosed shares stretches of homology that would encode some portion of a protein set forth in SEQ ID NO: 3, 5, 7 and 11. Lewis et al. teach the use of expression vectors to screen for inserts, therefore the proteins encoded by the sequences inserted in the vectors of the isolated clones serve a sequence capable of producing a protein that could serve and are capable of producing an immune response.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108.

The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David A. Montanari, Ph.D.



SUMESH KAUSHAL, PH.D.  
PRIMARY EXAMINER